REMARKS

This responds to the Office Action dated December 7, 2005 and the Advisory Action dated March 1, 2006. Claims 29, 30, 36-49, 51-54 and 58-59 are amended, no canceled and no claims are added herein. Thus, claims 1-60 remain pending in this application. Of these pending claims, claims 1-28 stand withdrawn from consideration.

Applicant amended claims to further clarify cardiac resynchronization therapy (CRT) and CRT-related data. No new matter is added. The amendments to the claims are believed to be supported throughout the specification, including at page 3 line 7-9, page 6 line 1 to line 29, and page 14 line 17 to page 17 line 9.

Examiner Interview

Applicant thanks Examiner Smith for the courtesy extended in discussing this application during brief telephone conferences with Applicant's attorney Marvin Beekman on April 3 and 4. The discussed subject matter was the current rejections to the claims. Agreement was not reached regarding the rejections. Examiner Smith requested further clarification of cardiac resynchronization therapy (CRT) and CRT-related data.

§102/§103 Rejection of the Claims

Claims 29-30 were rejected under 35 U.S.C. § 102(b) as being anticipated by Schroeppel et al. (U.S. Patent No. 5,749,900) or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Schroeppel et al. (U.S. Patent No. 5,749,900) in view of Stone et al. (U.S. Patent No. 6,280,409). Applicant respectfully traverses for at least the following reasons. Applicant is unable to find in Schroeppel et al. or the combination of Schroeppel et al. and Stone et al. a CRM device comprising, among other things, a controller adapted to control the prescribed CRT to improve coordination of ventricular contraction, and to control delivery of the pacing pulses, processing of the sensed signals, and recording of data to the memory, as recited in the amended claim. The prescribed CRT includes pacing a left ventricle cardiac site at a predetermined time interval with respect to a cardiac event at a second cardiac site. The cardiac event includes a paced cardiac event at the second cardiac site or a sensed intrinsic cardiac event at the second cardiac site. The

data includes data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site. Additionally, Applicant is unable to find in Schroeppel et al. or the combination of Schroeppel et al. and Stone et al. a CRM device comprising, among other things, a communication circuit adapted to transmit the recorded data to an external device for presentation of data trends useful to assess an efficacy of the prescribed CRT, wherein the data trends include at least one data parameter associated with time.

The rejection admits that Schroeppel et al. does not show the claimed CRM. Applicant has not found a reference to CRT, and respectfully submits that the A-A, P-P, V-V or R-R intervals represent heart rate data used in a statistical analysis of heart rate variability.

Stone et al. refers to a device that determines activity levels over a set of time periods (Abstract). The rejection asserts that FIGS. 4(a)-(c) discloses CRT-related data trends. However, FIGS. 4(a)-(c) plots activities per day against dates. Applicant respectfully submits that Stone et al. does not show, either in FIGS. 4(a)-(c) or elsewhere, data trends as recited in claim 29.

Thus, for at least these reasons, Applicant asserts independent claim 29 is in condition for allowance. Claim 30 depends on claim 29 and is in condition for allowance at least for the reasons provided with respect to claim 29. Applicant requests withdrawal of the rejection(s) and reconsideration and allowance of the claims.

§103 Rejection of the Claims

Claims 29-60 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stahmann et al. (U.S. Patent No. 6,480,742) in view of Stone et al. (U.S. Patent No. 6,280,409). Applicant respectfully traverses for at least the following reasons.

Three basic criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP §2142, citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir.1991).

Applicant respectfully submits that the combination does not show all of the language of the claims. MPEP 2143.03 states: "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)." Applicant also submits that the rejection does not provide an objective rationale for combining the references. "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions and cannot be dispensed with." *In re Sang-Su Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). "[The] factual question of motivation to combine is material to patentability, and could not be resolved on subjective belief and unknown authority." *Lee*, at 1343-44. "The board cannot rely on conclusory statement when dealing with particular combinations of prior art and specific claims, but must set for the rationale on which it relies." *Lee*, at 1343. Without such showings, there cannot be a reasonable expectation of success.

Applicant respectfully submits that the combination of Stahmann et al. and Stone et al. do not show a CRM device comprising, among other things, a controller and a communication circuit as recited in amended independent claim 29. The controller is adapted to control the prescribed CRT to improve coordination of ventricular contraction, and to control delivery of the pacing pulses, processing of the sensed signals, and recording of data to the memory. The prescribed CRT includes pacing a left ventricle cardiac site at a predetermined time interval with respect to a cardiac event at a second cardiac site. The cardiac event includes a paced cardiac event at the second cardiac site or a sensed intrinsic cardiac event at the second cardiac site. The data includes data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site. The communication circuit is adapted to transmit the recorded data to an external device for presentation of data trends useful to assess an efficacy of the prescribed CRT, wherein the data trends include at least one data parameter associated with time. Applicant also submits that the combination of Stahmann et al. and Stone et al. do not show a system comprising, among other

things, a CRM device and a programmer with a monitor, where at least one of the programmer and the CRM device is adapted to trend the data, as recited in amended independent claim 49. The data includes data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site. The monitor is adapted to display information corresponding to the trended data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site. Additionally, Applicant submits that the combination of Stahmann et al. and Stone et al. do not show a system comprising, among other things, a CRM device and a programmer, where the programmer includes means for displaying information corresponding to the trended data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, wherein the trended data include at least one data parameter associated with time, as recited in amended independent 54.

The rejection admits that Stahmann does not disclose data trends. The rejection asserts FIGS. 4(a)-(c) of Stone et al. discloses data trends that include at least one CRT-related data parameter associated with time. Applicant respectfully disagrees. FIGS. 4(a)-(c) plot activities per day against dates. Stone et al. refers to a device that determines activity levels over a set of time periods (Abstract). Applicant respectfully submits that Stone et al. does not show, either in FIGS. 4(a)-(c) or elsewhere, data trends indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site. Neither Stahmann et al. nor Stone et al. disclose the recited subject matter.

In Stahmann et al., cardiac cycles are classified and counted for use in CRT. The combination of Stone with Stahmann provides a device that classifies and counts cardiac cycles for use in CRT (Stahmann) and determines activity levels over a set of time periods (Stone). In addition to the reason that the combination does not include all of the claimed subject matter, Applicant submits that the rejection fails to provide a proper suggestion or motivation to combine the references. The asserted motivation to combine is "to provide feedback to the clinician during use of therapy and to indicate the total amount of some algorithmically derived measure of activity over a given period of time, such as day or an hour and to display formatted data in a human readable form." Applicant respectfully asserts that this reason does not provide

objective evidence why one would want to measure activity over a given time period as part of a cardiac resynchronization therapy. Further, Applicant respectfully asserts that the reason does not provide a reason why one would be motivated to progress from measuring activity over a given period of time to provide data trends indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site.

Thus, for at least these reasons, Applicant asserts independent claims 29, 49 and 54 are in condition for allowance. Claims 30-48 depend on independent claim 29; claims 50-53 depend on claim 49; and claims 55-60 depend on claim 54. These dependent claims are in condition for allowance at least for the reasons provided with respect to their base claim.

Claim 53 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stahmann et al. (U.S. Patent No. 6,480,742) and Stone et al. (U.S. Patent No. 6,280,409) as applied to claim 49 above, and further in view of Schroeppel et al. (U.S. Patent No. 5,749,900). Applicant respectfully traverses. Claim 53 depends on claim 49. As provided above, the combination of Stahmann et al. and Stone et al. do not support the rejection of claim 49. The addition of Schroeppel et al. does not cure the deficiencies of the rejection to claim 49. Thus, claim 53 is in condition for allowance for at least the reasons provided with respect to claim 49.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6960 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

JOHN A. DYJACH ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6960

Date 4-21-06

By _____
Marvin L. Beekman
Reg. No. 38,377

CERTIFICATE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 21 day of April 2006.

Paula Suchy
Name

Paula Suchy
Signature